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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,430	02/08/2002	Robert M. Platz	0008.15	3910

21968 7590 08/11/2003

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EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,430	PLATZ ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed 05/22/03 was entered. Claims 1 and 20 were amended. No claims were cancelled and no new claims were added.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-5, 12-15, 17-18 and 20-25 under 35 U.S.C. 102(e) as being anticipated by Backstrom et al (5,952,008) is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 6-11, 16 and 19 under 35 U.S.C. 103(a) as being unpatentable over Backstrom et al (5,952,008) in view of Kamei et al (5,575,987) is maintained.

Response to Arguments

Applicant's arguments filed 05/12/03 have been fully considered but they are not persuasive.

Applicant argues that Backstrom teaches "a mixture of active compounds (A) a pharmaceutically active polypeptide, and (B) an enhancer compound which enhances the systemic absorption", which is in contrast to the limitations of the amended claims. Applicant believes that the rejection should be withdrawn.

This is not found persuasive because the negative limitations added to the independent claims 1 and 20 are read in light of the specification, page 9. The specification does not include cyclodextrin in the list of peetration enhancers and therefore is not excluded from the composition. In fact, cyclodextrin is a compound of choice in the application, used as an excipient (see claim 5). Backstrom discloses cyclodextrin as one of the suitable promotion enhancers (see column 6, lines 23-26). It is noted that in examining product claims, it is sufficient for the prior art to show the components of a composition and regardless of what the component is classified under, the limitations are considered met. Therefore Backstrom reference, teaching compositions comprising spray-dried FSH and cyclodextrin is a proper prior art for the formulations of the instant application.

Applicant argues that combining Backstrom and Kamei references because a) there is no reason for success and b)Kamei does not teach the deficiency of Backstrom. This not persuasive. a) In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the knowledge generally available to one of ordinary skill in the art provides the suggestion and reasons for success and as shown by the supporting art of record, Kamei, use of amino acids and HSA as excipients, in pharmaceutical formulations is widely used and proven sucessful. B) Backsrom, as explained above, in fact does teach the primary elements of the invention's composition. Backstrom does not specifically teach use of some excipients such as amino acids and HSA. To show that these are well known and widely used excipients in the field of pharmaceuticals, Kamei reference was employed as the supporting prior art.

Applicant states that "In addition, Kamei et al lacks any disclosure with respect to pulmonary delivery....". This is found not commensurate with the scope of the claims. The instant claims are drawn to "a formulation...comprising...". Prior art of record meets and teaches all the required components of the formulation. The use of "for pulmonary delivery" language in a formulation claim is considered an "intended use", and according to the Office policies no weight is given to intended use in examination of composition claims .

Applicant argues that "Kamei describes including agents such as "Tween 80" in pharmaceutical preparations for oral administration. Applicants specifically identified Tweens as exmplery penetration enhancers in line 11 on page 9 of their specification". Applicant states that such penetration enhancers are "undesirable" in their preparations. This is not persuasive because Kamei discloses that "where necessary" agents

including Tween 80 are used as coating agents. Accordingly, Tween 80 is considered an optional component.

The following rejection, which was necessitated by the newly submitted IDS and amendments made to the independent claims, is made in addition to the existing rejections in the application.

Claims 1-6, 11-12, 16-22 and 25 are rejected under 35 U.S.C. **102(b)** as being anticipated by Hirai et al (4,659,696).

Hirai teaches a pharmaceutical composition which contains a hydrophilic drug and cyclodextrin, and methods of administering the composition to the patients nasal cavity (col. 1, lines 32-39). The hydrophilic drugs suitable for this formulation include polypeptides. Suitable polypeptides include follicle stimulating hormone (FSH) (col. 3, lines 45-60). The nasal preparation contains from about 0.005 to 50% w/v of polypeptide (col. 4, lines 61-63). The solid preparations may contain about 5 to 100 mg per dose of the polypeptide (col.6, lines 35-40). The polypeptides, cyclodextrin and an excipient, if required, are dissolved well in water and freeze-dried or spray-dried to give a dehydrated composition which is then pulverized into a solid preparation. The excipient is exemplified by glucose, mannitol, inositol, sucrose, lactose, fructose, etc (col. 5, lines 3-18). The preparations may contain buffers such as amino acids (col. 5, lines 48-55). Nasal preparations may be administered by an atomizer, spray-mist applicator and the like (col. 6, lines 23-33).

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 05/12/03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
August 8, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER